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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/489,079	01/21/00	BILLING-MEDEL	P	6451.US.P1

HM12/1024

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EXAMINER	
EPPS,J	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 10/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/489,079	Billing-Medel t al.
Examiner	**Group Art Unit**
Janet Epps	1635

☒ Responsive to communication(s) filed on *Jan 21, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-51* is/are pending in the applicat

Of the above, claim(s) *1-22, 26, 27, 30-35, 38, and 41-50* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *23-25, 28, 29, 36, 37, 39, 40, and 51* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4-6*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22, 32, 38, 41, and 45-49 drawn to a purified BS322 polynucleotide and methods of use of said polynucleotide, classified in class 536, subclass 23.1.

II. Claims 23-25, 28-29, 36-37, 39-40, and 51, drawn to a purified BS322 polypeptide and methods of use, classified in class 530, subclass 350+.

III. Claims 26-27, 30-31, 33-35, 42-44, and 50, drawn to a specific agent that binds to the BS322 polypeptide, including antibodies, and methods of detecting BS322 antigen in a test sample and a test kit comprising agents that bind to the BS322 polypeptide, classified in class 424, subclass 130.1+.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to chemical compositions that are chemically, structurally, and functionally distinct. Furthermore, the methods of group I can only be used with the claimed polynucleotide of this group and can therefore not be practiced with the polypeptide of group II or the antibody or binding agent of group III. In a similar manner, the methods of use of the polypeptides of group II can not be practiced with the antibody of group III.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II or Group III, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Mimi C. Goller on 10-16-00 a provisional election was made without traverse to prosecute the invention of Group II, claims 23-25, 28-29, 36-37, 39-40, and 51. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-22, 26-27, 30-35, 38, 41-50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Specification

8. The specification is objected to because of the following informalities: sequence identifiers are recited in the specification as "SEQUENCE ID NO", this term should be replaced with "SEQ ID NO: ". Appropriate correction is required. (See 37 CFR 1.822 and 1.823)

Claim Objections

9. Claims 23-25, 28-29, 36-37, 39-40, and 51 are objected to because of the following informalities: sequence identifiers are recited in these claims as "SEQUENCE ID NO", this term should be replaced with "SEQ ID NO: ". Appropriate correction is required. (See 37 CFR 1.822 and 1.823)

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 23-25, 28-29, 36-37, 39-40, and 51 are rejected under 35 U.S.C. 101 because Applicants have disclosed at least one specific and substantial utility for the claimed invention, but the assertion is not credible, therefore the claimed invention lacks patentable utility. Applicants teach that detecting the presence of the BS322 polypeptide is indicative of the presence of breast disease. However, the specification as filed does not make a positive assertion that detecting the presence of a BS322 polypeptide indicates "a diagnosis of a breast tissue disease or condition such as breast cancer." The specification as filed teaches that the BS322 consensus sequence was found in 23.2% (10 of 43) breast tissue libraries and found in only 0.1% (1 of 762) of other, non-

breast libraries. These finding do not indicate whether or not the breast tissue libraries or the other non-breast libraries were derived from malignant, or diseased ~~or~~ cells. The use of non-breast libraries as a control to breast tissue libraries is inappropriate since the specification as filed does not indicate that the non-breast libraries were derived from "normal" tissues, i.e. non-diseased tissues. To correlate the presence of the BS322 polypeptide with the presence or absence of a breast disease is entirely premature since the evidence set forth does not support this conclusion.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 23-25, 28-29, 36-37, 39-40, and 51 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

14. Claims 23-25, 28-29, 36-37, 39-40, and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 23-25, 28-29, 36-37, 39-40, and 51 recite a BS322 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID

NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.

These claims read on a genus of polypeptides. However, neither the claims or the specification as filed indicate what distinguishing attributes are shared by the members of the claimed genus of polypeptides. The specification and claims do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the claim polypeptides, it is only required that a protein maintains 50% identity to the claimed polypeptide sequences. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between the genus members is permitted, and neither the specification or the claims provide any guidance as to what specific changes should be made. Furthermore, there are no common functional attributes shared among the members of the claimed genus of polypeptides that would allow one of skill in the art to clearly distinguish the members of this genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is required. Since the disclosure fails to describe the common attributes or characteristics that identify the members of the genus, and because the genus is highly variant, the disclosed sequences alone are not sufficient to describe the claimed genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 23-25, 28-29, 36-37, 39-40, and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23, 26, 28, 36, 39-40, and those dependent therefrom, recite "and fragments thereof". By convention there should be only one invention recited per claim. Claim 23 reads on multiple "fragments thereof", there is ambiguity as to whether the claim reads on one particular fragment or multiple fragments.

Claims 28 and 36 recite the limitation "the presence", there is lack of antecedent basis for this limitation in these claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps whose telephone number is (703) 308-8883. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax number for this group is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet L. Epps, Ph.D.

October 23, 2000

ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER